

dialing 888-946-7207, passcode: 5023213. A total of 200 lines will be available. To register for this call, please go to [www.cdc.gov/hicpac](http://www.cdc.gov/hicpac).

**DATES:** The meeting will be held on February 15, 2018, 12:00 p.m. to 2:00 p.m., EST.

**ADDRESSES:** Teleconference Number: 888-946-7207, passcode: 5023213

**FOR FURTHER INFORMATION CONTACT:** Erin Stone, M.A., HICPAC, Division of Healthcare Quality Promotion, NCEZID, CDC, 1600 Clifton Road NE, Mailstop A-31, Atlanta, Georgia 30333; Email: [HICPAC@cdc.gov](mailto:HICPAC@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

*Purpose:* The Committee is charged with providing advice and guidance to the Director, Division of Healthcare Quality Promotion (DHQP), the Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), the Director, CDC, the Secretary, Health and Human Services regarding (1) the practice of healthcare infection prevention and control; (2) strategies for surveillance, prevention, and control of infections, antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of CDC guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

*Matters To Be Considered:* The agenda will include discussions from the recommendation categorization update workgroup, the guidelines for infection prevention in healthcare personnel workgroup, and the guidelines for infection prevention in patients of neonatal intensive care units workgroup. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Claudette Grant,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2017-28072 Filed 12-27-17; 8:45 am]

**BILLING CODE 4163-19-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-N-6888]

**Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will be held on March 1, 2018, from 8 a.m. to 6 p.m.

**ADDRESSES:** Hilton Washington, DC North/Gaithersburg, 620 Perry Pkwy., Salons A, B, C, and D, Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**FOR FURTHER INFORMATION CONTACT:**

Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993-0002, [Aden.Asefa@fda.hhs.gov](mailto:Aden.Asefa@fda.hhs.gov), 301-796-0400, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* On March 1, 2018, the committee will discuss, make recommendations, and advise FDA regarding the evaluation of clinical study data to support the safety and

effectiveness of intracranial aneurysm treatment devices and factors that can affect clinical outcomes such as aneurysm morphology, size, and location in the neurovasculature. FDA is also convening this committee to seek expert opinion on the scientific and clinical considerations relating to the clinical trial design that may be relevant to the determination of safety and effectiveness for these devices.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 19, 2018. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 12, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 16, 2018.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at [Annmarie.Williams@fda.hhs.gov](mailto:Annmarie.Williams@fda.hhs.gov) or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 21, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-27974 Filed 12-27-17; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-6778]

#### Fostering Medical Innovation: Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA or Agency or we) Center for Devices and Radiological Health (CDRH or Center) is announcing its Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot Program (CfQ Pilot Program). The CfQ Pilot Program is voluntary and intends to evaluate product and manufacturing quality within the medical device ecosystem. The CfQ Pilot Program also intends to explore the effectiveness of a quality maturity appraisal, the use of objective metrics, optimization of resources, and impact on quality culture. The pilot program seeks to demonstrate better patient safety and outcomes, a lower regulatory burden on demonstrating quality assurance, and assure safety and effectiveness during product development and manufacturing.

**DATES:** The CfQ Pilot Program will run from January 2, 2018, to December 28, 2018. See the "Participation" section for instructions on how to submit a request to participate.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2017-N-6778 for "Case for Quality Voluntary Medical Device Manufacturing and Product Quality Program." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Francisco Vicenty, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3426, Silver Spring, MD 20993, 301-796-5577, [Francisco.vicenty@fda.hhs.gov](mailto:Francisco.vicenty@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

As part of CDRH's 2016-2017 strategic priority to "Promote a Culture of Quality and Organizational Excellence" (Ref. 1), CDRH envisions a future state where the medical device ecosystem is inherently focused on device features and manufacturing practices that have the greatest impact on product quality and patient safety. Historically, FDA has evaluated manufacturers' compliance with regulations governing the design and production of devices. Compliance with the Quality System regulation, 21 CFR part 820, (Ref. 2) is a baseline requirement for medical device manufacturing firms. Focusing on elevating manufacturing quality practices gives greater emphasis to these practices, which should correlate to higher quality outcomes. This allows FDA to adjust how we recognize and incentivize behaviors and processes through which the safety and effectiveness of a medical device is